

**REMARKS**

This is a Reply to a Final Office Action mailed November 6, 2009 by the United States Patent and Trademark Office (Patent Office).

**Summary of Prosecution To-Date**

In a telephone interview of October 29, 2007, the details of each of the cited references relied upon by the Examiner in a previous Office action of May 18, 2007, and of an Amendment that Applicants filed on October 18, 2007, were discussed. As stated in the Interview Summary prepared by the Patent Office and mailed on November 1, 2007, the Examiner argued that “Beard ’296 could reasonably be seen to disclose an ankle foot orthosis that varies impedance of the ankle joint,” and that Applicant, “in order to overcome this interpretation,... proposed that Beard ’296, although possibly seen as impeding movement of the ankle joint, does not modulate the joint stiffness or joint damping property when providing such impedance.” In other words, as summarized by the Examiner:

The impedance provided by Beard ’296 is all or none, wherein during the swing phase the foot is locked to prevent movement (foot drop), and upon heel strike the slip coupling effectively unlocks the joint to again allow free movement of the device and the ankle. A simple lock and release control of the ankle does not equate to modulating the mechanical properties of stiffness or damping exhibited by the joint.

The Examiner suggested, as alternatives, that the claims would be “amended to convey that the impedance is being modulated continuously or more than once in an updating manner”, or “to include a limitation wherein the modulation to the joint impedance is adaptive in nature.” The Examiner summarized the remaining references as lacking the teachings that were also found lacking in Beard ’296. For example, with respect to Swain ’757, the Examiner stated that, although Figures 2-4 show a rising edge ramp and falling edge ramp in a stimulation pattern, “these edge regions are found to be negligible artifacts of real versus ideal control systems, and would not be sufficient to provide modulation of ankle joint stiffness.” The Examiner found that

Swain '757 lacked "disclosure of modulating the mechanical properties of stiffness and damping in the ankle joint in an adaptive manner."

The Examiner also found that Stein '332 was "deficient in disclosing modulation of stiffness and damping in the ankle joint," because Stein '332 "again discloses a system in which the joint is either locked at an upward position to avoid the toe strike or fully released to allow free motion during heel strike and walk-over."

The Examiner stated that Johnson '693 "similarly discloses a system with an all-or-none foot lift during swing and release during heel strike" and that, "[a]lthough the Johnson '693 system employs a pneumatic actuator with a series spring (Figure 3C), the spring constant  $k$ , which in this system represents the joint stiffness, stays constant regardless of the position or amount of contraction of the pneumatic actuator." Because "varying of the joint impedance would require a varying of the constant  $k$ ," the Examiner stated that "Johnson '693 again lacks modulation of the stiffness and damping in the ankle joint."

Finally, with respect to Horst '882, the Examiner stated that this reference "similarly discloses a system with a dc motor actuator which, for reasons similar to the other discussed references, lacks the ability to modulate the mechanical stiffness and damping properties of the ankle joint in an adaptive manner."

Therefore, the Examiner at least appeared to acknowledge that none of the references taught modulation of an ankle joint, nor did any of the references teach modulation of an ankle joint in an "updating manner" or in a manner that is "adaptive in nature." The Examiner indicated in the interview summary that agreement was reached.

Thereafter, on November 9, 2007, Applicants mailed a Supplemental Amendment to follow up the interview that was conducted, and amended the claims to specify that Applicants' claimed device modulates a joint stiffness or damping of an ankle joint during walking for treating an ankle foot gait pathology. Although the claims prior to amendment had all specified that the device modulated impedance, and therefore did not read on any of the references cited by the Examiner, Applicants believe that by substituting the term "modulates impedance," with the phrase "modulates a joint stiffness or damping" of an ankle joint, would clarify what was meant by the modulation of Applicants' variable-impedance active ankle foot orthosis.

On May 28, 2008, the Examiner issued an Office Action stating that, despite the fact that the "Examiner suggested therein that to overcome the art, the claims could be amended to

convey that the impedance is being modulated continuously or at least successively throughout a swing phase and a walking cycle to better state the inventive concept of adaptive/updating/variable/learning modulation of ankle impedance or stiffness or damping throughout the gait cycle,” the claims as presented in the Amendment of November 13, 2007 lacked these features, “merely reciting modulation during walking.” The Examiner further stated that given “this broadest reasonable interpretation,” walking “would require only a teaching of a singular, non-adaptive change in the variable at any arbitrary point during walking movement.” The Examiner then reiterated all of the novelty rejections previously made, apparently not recognizing a distinction between “on/off” change in impedance described in the cited references and “modulation” of impedance of Applicants’ claimed device, as described in the interview summary prepared by the Examiner and with which the Examiner had apparently agreed. The Examiner did not identify any teachings in the references cited and made a new rejection, over Goffer (U.S. 2003/0093021, hereinafter Goffer ’021) of Claim 31. No other new rejections were made. Therefore, the Examiner apparently failed to recall the distinction made during the telephone interview conducted on October 29, 2007 in his May 2008 Office Action between “on/off” variable impedance and “modulation” of impedance, or refused to acknowledge it in the Office action issued in May 2008.

Nevertheless, in an Amendment filed on August 26, 2008, Applicants amended the claims to recite that the claim device modulates joint stiffness or damping of an ankle joint “in an updating manner at least twice” during “each walk cycle” in order to comport with the Examiner’s understanding of what was agreed to during the telephone interview of October 29, 2007. Five new claims were also added along the same lines, specifying that modulation of joint impedance by the claimed device is “adaptive in nature,” which the Examiner also recited as a suggestion he had made during the telephone interview of October 29, 2007. An Advisory Action was issued on September 23, 2008, and Applicants filed a Request for Continued Examination on October 14, 2008.

On February 25, 2009, an Office action was issued by the U.S. Patent and Trademark Office rejecting all 41 claims. In the section entitled “Response to Arguments,” the Examiner stated that Applicants claimed device, which modulates “in an updating manner at least twice during each walking cycle,” read upon references that operate in a “locking/unlocking fashion as has been previously discussed.” The Examiner explained that “[s]uch a method qualifies as

updating at least twice per cycle, since the device first pulls or locks the foot in an upwardly flexed position in late stance or early swing, and then releases the locking mechanism on heel strike to satisfy the criteria of updating a second time during the same cycle.” Further, the Examiner stated that, with respect to new Claims 37-41, it “is also noted that these devices and methods are considered to read on the language of a modulation that is adaptive in nature, since information from each gait cycle is inherently used in modulating device function.”

Therefore, the Examiner, further to his previous failure to acknowledge a distinction between “on/off” variability in impedance and “modulation” of impedance, as previously discussed in the telephone interview of October 29, 2007, now failed or refused to recognize a distinction between “adaptive/updating/variable/learning modulation of ankle impedance or stiffness or damping throughout the gait cycle,” which he had suggested during the telephone interview of October 29, 2007, and acknowledged as an inventive concept of Applicants’ claimed invention in his Office Action of May, 2008 relative to the same references he had been reciting since the first Office Action issued in this case on May 18, 2007. In other words, since October 29, 2007, the Examiner, with each Office action, progressively failed to recognize a distinction acknowledged in each previous Office action over the same references. Applicants do not understand how the Examiner can reasonably successively rescind positions previously taken with each succeeding Office action. Prosecution of a patent application in this matter is worse than piece-meal prosecution in that it actively suggests amendments to the Applicant that might be made to gain allowance of the application and then actively rescinds those same suggestions, thereby forcing the Applicant to continue prosecution at significant expense and considerable delay.

On April 2, 2009, Applicants conducted a second telephone interview with Examiner Flory and his supervisor, Mr. George Manuel. During the interview, according to the Interview Summary prepared by the Examiner and mailed from the U.S. Patent and Trademark Office on April 6, 2009, Applicants proposed changing the limitation of updating “at least twice” to updating “at least three times” in order to overcome the applied references. Applicants also discussed with the Examiner modulation of joint stiffness and ankle damping by “computer-controlled modulation,” rather than by “passive or inherent features of the device itself.” The Examiner stated in the interview summary that he “agreed that such changes would at least overcome the Beard reference, and agreed to take a thorough look at the remaining art in light of

the proposed changes.” Applicants amended the claims accordingly in an Amendment that was filed on April 8, 2009.

On November 6, 2009, an Office action was issued, again rejecting all 41 claims. The Office action was made final. The Examiner stated in the Office action that “it was only agreed upon that [if] both amendments (‘computer-controlled modulation’) and (‘updating at least three times’) were made to each of the independent claims, then only the Beard reference as applied would be overcome.” Having restated his agreement, the Examiner, under paragraph 6 on page 3, then stated that, “[f]or those references where only two updates per cycle are disclosed (Beard ’296, Swain ’757, Goffer ’021), it is considered obvious to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art.” Applicants can only understand the Examiner to mean that, despite the fact that he is admitting in the Office action that although he agreed that Beard would be overcome by including both limitations of “computer-controlled modulation” and “updating at least three times,” he, nevertheless, is rejecting all 36 claims over Beard ’296, among other references, because “it is considered obvious to update a third time during this cycle.” Applicants can only conclude that the Examiner, within the same Office action, is both admitting patentable distinction of claimed subject matter over a reference and then subsequently rejecting that same claimed subject matter over the same reference.

#### Response to Current Rejections

The remainder of the reply responds to the most recent rejections, set forth in the Office Action made Final, mailed on November 6, 2009.

#### Rejection of Claims 37 and 39 Under 35 U.S.C. § 102(b) in View of Beard ’296

Claims 37 and 39 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Beard et al. (U.S. Patent 5,112,296, hereinafter Beard ’296). Specifically, the Examiner stated that, with respect to Claim 37, Beard ’296 discloses a variable-impedance active foot orthosis for modulating a joint stiffness or damping of an ankle joint at least twice during each walking cycle for treating an ankle foot gait pathology, wherein the pathology comprises foot drop. With respect to Claim 39, the Examiner stated that Beard ’296 discloses a method of modulating joint

stiffness or damping of an ankle joint of an orthosis at least twice during each walking cycle wherein the method includes adjusting the stiffness of the joint during controlled plantar flexion and minimizing impedance during late stance.

Beard '296 discloses a biofeedback activated orthosis configured for foot-drop rehabilitation. The orthosis includes foot brace 2 secured to the foot of the user that includes lifting cable 3 for lifting foot 54 throughout a gait cycle. (See Col. 4, lines 40-43). Beard '296 also discloses a device 8 for sending a signal to a controller to represent an angular relationship between the lower leg and the thigh (See Col. 4, lines 60 through Col. 5, line 383). If both muscle activity parameters and the angular relationship between the lower leg and the thigh are met, then a processing signal is sent to activate geared motor 29 to timely apply tension to the cable and to pull upwardly foot brace 2. (See Col. 5, lines 48-58).

Applicants claim a variable-impedance active ankle foot orthosis device. In one embodiment, the device includes an actuator and a spring. The spring is linked to the actuator. The actuator modulates or selectively varies an impedance of the ankle joint by controlling the spring. This modulation is not disclosed or suggested by Beard et al.

One embodiment of Applicants' claimed invention is described at pages 4-5 and Fig. 1, which discloses that the actuator 12 includes a brushless DC motor operatively connected in series with a spring. The actuator provides force control by controlling the extent that the spring is compressed. In another embodiment, the orthosis device further includes sensors 14 and 16, or more particularly, a ground reaction sensor and an ankle angle sensor to provide feedback to the actuator, which then modulates an impedance of an ankle joint by controlling the spring.

The Beard '296 device is not a variable-impedance active ankle orthosis. The Examiner's cited passages do not disclose or suggest any variable-impedance active ankle orthosis. The Beard '296 device simply does not modulate the impedance of the ankle joint.

The Examiner also stated, that with respect to Claim 37, that "there is inherently a joint formed between the leg portion 4 and foot portion 2" of the device disclosed by Beard '296. The Examiner further stated that, "alternatively, the knee orthotic joint 8 can also be considered to anticipate the claims as written, since it is not specified that the joint be the ankle joint, but rather that the joint be related to treatment of an ankle foot gait pathology." Regarding Claim 39, the Examiner stated that "[i]t is noted that the joint between the leg portion and the foot portion inherently exists and is inherently modulated throughout the gait." Further, the Examiner stated

that “[i]t is also noted that the impedance of the knee orthotic joint is modulated throughout the walking cycle, and therefore, anticipated the claims.”

The Examiner’s assertion that the variable impedance of Applicants’ claimed invention is inherent in the “joint” between the leg portion 4 and the foot portion 2 is erroneous since there is no joint between the leg portion 4 and the foot portion 2. Moreover, Applicants’ system selectively varies, or selectively changes, the impedance of an ankle joint, while Beard ‘296 simply uses feedback to activate the motor and to pull the cable 3, and to pull upwardly the foot brace 2.

In addition, if it is the Examiner’s assertion that the impedance of the ankle joint of the individual is what is being modulated, this too is also erroneous. Applicants contend that the impedance of the ankle joint between the leg and the foot (when the individual is wearing the Beard ‘296 device) is the same throughout the walking cycle and is not modified or varied. The cable 3 of the Beard ‘296 device simply lifts the foot 54 throughout a walking or gait cycle.

Moreover, simply because the cable 3 lifts the foot 54 throughout a gait cycle does not mean that the impedance of the ankle joint is varied or modulated, let alone actively and throughout the walking cycle. This varying impedance throughout a walking cycle is especially advantageous since Applicants’ device can vary impedance quickly in response to gait speed of the individual. (See Applicants’ specification at page 8, lines 19-28). Applicants respectfully submit that the individual’s ankle joint wearing the Beard ‘296 device has the same impedance regardless of whether the foot is being lifted by the cable 3 or not.

The Examiner is mistaken by equating merely lifting the foot with Applicants’ device for modulating or selectively changing an impedance of the ankle joint throughout a walking cycle for treating an ankle foot gait pathology. The Beard ‘296 device does nothing to change the impedance of the ankle joint, and simply provides a tensile force to the foot about the foot portion.

Finally, the assertion that the knee joint is considered to anticipate the claims is also erroneous, since, again, the impedance of the knee joint is unchanged by the Beard ‘296 device. At most, Beard ‘296 discloses that a backlash inhibiting device 67 prevents backlash at cable 3 by maintaining a minimum amount of tension in cable 3 at all times. Beard ‘296 does not modulate any impedance of the ankle joint, nor is an ankle joint selectively controlled as presently claimed in independent Claims 37 and 39.

Reconsideration and withdrawal of the rejection of independent Claims 37 and 39 are respectfully requested.

Rejection of Claims 24 and 33-36 Under 35 U.S.C. § 102(b) in View of Stein '332

Claims 24 and 33-36 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,643,332, issued to Stein (hereinafter Stein '332). In particular, the Examiner stated that Stein '332 clearly outlines a FES stimulation device and method which modulates ankle stiffness during the swing phase of a walking cycle, which inherently provides control during controlled plantar flexion and minimizes forefoot collision. Regarding modulation during the swing phase, the Examiner made reference to Col. 6, lines 34-55.

Stein '332 teaches an electrical stimulation device which causes a depolarization of the underlying membrane, and which causes propagation of an impulse along the nerve and contraction of the muscle. Stein '332 does not disclose or suggest modulating joint stiffness or damping, as claimed by Applicants. Col. 6, lines 34-55 of Stein '332 do not, as asserted by the Examiner, teach modulation during a swing phase, but rather an on/off electrical stimulation which, as the Examiner had previously stated in an Interview Summary dated November 1, 2007, is "deficient in disclosing modulation of stiffness and damping in the ankle joint," because Stein '332 "again discloses a system in which the joint is either locked at an upward position to avoid the toe strike or fully released to allow free motion during heel strike and walkover."

Therefore, independent Claim 24, and Claims 33-36, which depend from independent Claim 24, are novel in view of Stein '332 under 35 U.S.C. § 102(b). Reconsideration is respectfully requested.

Rejection of Claims 1-9, 11-23, 25-29, 32 and 37-40 Under 35 U.S.C. § 102(b) in View of Johnson '693

Claims 1-9, 11-23, 25-29, 32 and 37-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,662,693, issued to Johnson, et al. (hereinafter Johnson '693). The Examiner stated that particular emphasis is placed on the abstract, Figs. 1, 3C, 5 and 9; and Col. 8, lines 4-14; Col. 9, lines 3-27; and Col. 10, lines 55-65.

Johnson '693 discloses an exo-skeleton that is capable of providing a normal person with additional strength and support, thereby creating a state of super mobility. (See Col. 6, lines 53-



59). The exo-skeleton includes an apparatus that includes braces that reinforce four segments of the patient's legs. In one embodiment, the person may have a mobility impairment below the ankle, the knee or the upper thigh. (See Col. 6, lines 60-67). These braces cover the entire leg and is not an active ankle foot orthosis.

The braces included pneumatic actuators to allow for various force states of the brace. The actuators provide contractile forces about a joint 113 creating and sustaining torque required for mobility enhancement or stability. (See Col. 7, lines 26-35).

Col. 8, lines 5-34 disclose that, in a human ankle joint, contractile forces that are associated with the ankle joint include a large force in the foot plantation movement and a relatively smaller toe lift force. Johnson discloses that a spring can be provided to substitute for an opposing muscle in a lopsided torque requirement to balance forces between the foot plantation movement and the toe lift.

Col. 8, lines 15-25 of Johnson discloses that integration of goniometric inputs from the fingers, control actuators, and sensors make the active orthosis function as a functioning mobility assist device. However, Johnson does not disclose or suggest a device for modulating an impedance of an ankle joint throughout a walking cycle for treating an ankle foot gait pathology. In contrast, Johnson discloses an exo-skeleton that provides the forces necessary for the walking cycle. (See Col. 2, lines 5-28).

Johnson does not disclose or suggest modulating an impedance of the ankle joint throughout a walking cycle, but instead discloses providing contractile forces to joints associated with the exo-skeleton to provide mobility. Johnson discloses that the patient using the brace can set the amount of stiffness of the legs for any force or load. This provides that the legs wearing the brace can be self-stable. This is not the same as modulating an impedance of the ankle joint throughout a walking cycle for treating an ankle foot gait pathology.

Claim 1 is novel under 35 U.S.C. § 102(b) and, therefore, reconsideration and withdrawal of this rejection are respectfully requested. Claims 2-9, 11 and 26-29 depend from Claim 1, and are patentable for at least the reasons discussed above for Claim 1. Independent Claims 12 and 19 are also patentable for at least the same reasons discussed above for Claim 1. Claims 13-18 depend from Claim 12 and are patentable for at least the same reasons discussed above for Claim 12. Claims 20-23, 29-30 and 32 depend from Claim 19 and are patentable for at least the same

reasons discussed above for Claim 19. Claims 37-40 are all independent Claims, and are patentable for the same reasons discussed with respect to independent Claim 1 above.

Rejection of Claims 1-4, 6-8, 11-23, 25-30, 32 and 37-40 Under 35 U.S.C. § 102(e) in View of Horst '882

Claims 1-4, 6-8, 11-23, 25-30, 32 and 37-40 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 6,966,882 to Horst et al. (hereinafter Horst '882). The Examiner stated that "particular emphasis is given to the abstract, Figs. 1 and 4-6 and related paragraphs, particularly as pertains to assist, monitor, and rehabilitate modes 508-512 to address the adaptive nature of the modulation. Further, the Examiner stated that Horst '882 discloses computer-controlled actuation in Col. 3, lines 41-58 and updating at least three times per walk cycle in Col. 5, lines 63 through Col. 6, line 28.

Horst discloses a braced device which is attached at the knee. The structural frame of the device includes pair of hinges 18 at the medial and lateral sides of the brace. (See Column 5, lines 1-15). The brace device also includes an actuator 12 that is coupled to the brace to provide the force needed to assist or resist the leg muscle during rotation. The actuator 12 includes a rotary motor. The rotary motor has a center of rotation which is located close to a center of rotation of the knee joint (See Col. 7, lines 28-44). Horst '882 does not disclose or suggest a device for modulating an impedance of an ankle joint throughout a walking cycle for treating an ankle foot gait pathology. In contrast, Horst '882 discloses a brace device for rotating a knee joint to assist or resist (for an exercise) a primary movement direction of a leg muscle. (See Col. 7, lines 18-26). At most, Horst '882 discloses that the device may be used to assist with rotation of an ankle joint at Col. 7, line 25. However, Horst '882 does not disclose or suggest modulating an impedance at the ankle throughout a walking cycle for treating an ankle for gait pathology. In contrast, Horst '882 discloses providing a rotating force to a portion of a brace located at the knee joint using a number of sensors. This is not modulating and impedance of the ankle joint throughout a walking cycle, and Claim 1 is novel under 35 U.S.C. § 102(e).

Reconsideration and withdrawal of this rejection of Claim 1 are respectfully requested. Claims 2-4, 6-8, 11 and 26-28 depend from Claim 1 and are patentable for at least the reasons discussed above for Claim 1. Independent Claims 12, 19 and 25 are also patentable for at least the reasons discussed above for Claim 1. Claims 13-18 depend from Claim 12 and are

patentable for at least the same reasons discussed above for Claim 12. Claims 20-23, 29-30 and 32 depend from Claim 19 and are patentable for at least the same reasons discussed above for Claim 19. Claims 37-40 are all independent claims and are patentable for at least the reasons discussed with respect to Claims 1, 12, 19 and 25.

Rejection of Claim 41 Under 35 U.S.C. § 102(e) in View of Goffer '021

Claim 41 stands rejected under 35 U.S.C. § 102(e) as being clearly anticipated by U.S. Publication No. 2003/0093021, to Goffer (hereinafter Goffer '021). In particular, the Examiner referred to selected paragraphs of Goffer '021 as describing a method of treating an ankle foot gait pathology use in functional electrical stimulation in conjunction with a traditional orthosis or brace. Further, the Examiner restated that Goffer '021 discloses computer-controlled actuation.

As with the references previously cited by the Examiner, Goffer '021 does not disclose method of treating an ankle foot gait pathology employing electrical pulses to elicit muscle contractions to actively modulate, by computer-controlled actuation, ankle stiffness or damping, or both, wherein modulation of joint impedance is adaptive in nature, whereby information from each gait cycle causes further modulations that vary in joint impedance from one gait cycle to the next, wherein joint stiffness or damping or both are further modulated by controlling a spring associated with an orthosis as claimed by Applicant. Therefore, Goffer '021 does not anticipate the subject matter of Applicant's independent Claim 41.

Rejection of Claims Under 35 U.S.C. § 103(a) in View of Beard '296

Claims 1, 2, 4, 6-8, 10, 11, 19, 20, 22, 29 and 30 stated rejected under 35 U.S.C. § 103(a) in view of Beard '296. In particular, the Examiner stated that "Beard '296 is considered to disclose the invention substantially as claimed including adaptive and updating control of joint stiffness or damping, but does not expressly disclose that the updating occurs at least three times during each walk cycle." The Examiner stated that it "would have been obvious to one of ordinary skill in the art at the time of the invention to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art."

Claims 1 and 19 of this rejection are independent, and the remaining claims are dependent from either independent Claims 1 or 19. As discussed above with respect to Claims

37 and 39, Beard '296 does not disclose modulation of joint stiffness or damping of an ankle joint in an updating manner of a variable-impedance active ankle foot orthosis, as claimed by Applicants in independent Claims 1 and 19. Therefore, the Examiner's characterization of Beard '296 as including all of the limitations of Claims 1 and 19, except that of updating three times during each walking cycle, is incorrect.

There is no disclosure or suggestion, nor would one of ordinary skill in the art be motivated to modify the teachings of Beard '296 to obtain Applicants' claimed variable-impedance active ankle foot orthosis and method, as claimed in independent Claims 1 and 19, respectively. As a result, Applicants' claimed subject matter of independent Claims 1 and 19, and claims dependent therefrom, meet the requirements of 35 U.S.C. 103(a) in view of Beard '296.

Rejection of Claim 9 Under 35 U.S.C. 103(a) in View of Beard '296, Swain '757 or Naft '503

Claim 9 stands rejected as being unpatentable under 35 U.S.C. 103(a) in view of Beard '296, in view of U.S. 6,507,757, issued to Swain, et al. (hereinafter Swain '757) or in view of U.S. 6,517,503 to Naft, et al. (hereinafter Naft '503). In particular, the Examiner stated that Beard '296 discloses the invention substantially as claimed but does expressly disclose a foot switch. Accordingly, the Examiner stated that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard '296 with the foot switch of either Swain '757 or Naft '503 to provide the Beard '296 system with the same advantage of improving patient gait and treating drop foot ("motivation to combine provided by the abstracts of Swain et al. and Naft et al.").

Claim 9 depends from independent Claim 1 and, therefore, contrary to the Examiner's statement, Beard '296 does not disclose the invention substantially as claimed but for the presence of a foot switch. As stated above, Beard '296 does not disclose or suggest, nor would one of ordinary skill in the art be motivated in view of Beard '296, to modify the teachings in Beard '296 to include modulation of joint stiffness or damping of an ankle joint in an updating manner, as does Applicants' claimed and variable-impedance active foot orthosis. Neither Swain '757 nor Naft '503 remedy the deficiencies of Beard '296. Therefore, dependent Claim 9 meets the requirements of 35 U.S.C. § 103(a), in view of Beard '296, Swain '757 and Naft '503, taken separately or in any combination.

Rejection of Claims 24 and 33-36 Under 35 U.S.C. 103(a) in View of Swain '757

Claims 24 and 33-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Swain '757. In particular, the Examiner stated that Swain '757 clearly discloses the invention as claimed with the exception of updating at least three times during each walk cycle. The Examiner stated that it "would have been obvious to one of ordinary skill in the art at the time of the invention to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein repetition of steps in a known process involves only routine skill in the art.

As discussed above, Swain '757 lacks disclosure of modulating of mechanical properties of stiffness and damping in the ankle joint in an adaptive manner," as stated by the Examiner in an Interview Summary prepared by the Examiner mailed from the United States Patent and Trademark Office on November 1, 2007. Therefore, Swain '757 fails, as does Beard '296 and all other references cited by the Examiner in other rejections of Claim 24 and Claims 33-36, which depend from Claim 24, to disclose or suggest, or provide motivation to one of ordinary skill in the art, to obtain Applicants' claimed method of treating an ankle foot gait pathology.

Rejection of Claim 31 Under 35 U.S.C. § 103(a) as Being Unpatentable Over Goffer '021

Claim 31 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Goffer '021. In particular, the Examiner stated that Goffer '021 discloses the invention substantially as claimed, but does not expressly disclose that the updating occurs at at least three times per walk cycle, and that it would have been obvious to one of ordinary skill in the art at the time of the invention to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art.

As discussed above with respect to independent Claim 41, Goffer '021 does not disclose or suggest, nor would one of ordinary skill in the art be motivated to modify the teachings of Goffer '021 to obtain a method for treating an ankle foot gait pathology using functional electrical stimulation by applying computer-controlled electrical pulses to elicit muscle contractions to actively modulate ankle stiffness or damping, or both in an updating manner during each walking cycle, wherein the joint stiffness or damping are modulated by controlling

the spring associated with orthosis, as claimed by Applicant. Therefore, Applicants' method, as claimed in independent Claim 31, meets the requirements of 35 U.S.C. § 103(a) in view of Goffer '021.

### **SUMMARY AND CONCLUSIONS**

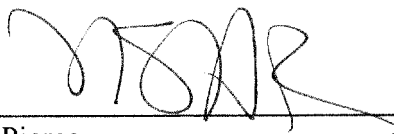
Applicants are filing another Request for Continued Examination with this Reply. Applicants make no admissions regarding the relevance of prior art by any amendments that have been made during the course of prosecution of this application.

Applicants maintain current Claims 1-41. Applicants believe the pending claims all meet the requirements of 35 U.S.C. §§ 102 and 103, in view of the references cited by the Examiner, and believe that they are in condition for allowance. Applicants respectfully request an oral interview at the Patent Office with the Examiner at his earliest convenience.

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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